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## **REMARKS/ARGUMENTS**

Claims 28-51, 53-58 and 82-120 were previously pending and presented for examination on the merits. Claims 28, 29, 30, and 42 are herein amended. After entry of these amendments, claims 28-51, 53-58, 82, and 84 to 120 will be pending.

Response to the rejection of claims 42-51 and 53-55 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for chlorine ion, is alleged to not reasonably provide enablement for counterion.

Without acquiescing on the merits and in order to expedite prosecution, the Applicants have amended the affected claims to set forth that the counterion is Cl<sup>-</sup>. Accordingly, the Applicants respectfully request that the above grounds for rejection be reconsidered and withdrawn.

Response to the rejection of claims 28-30, 32-41, 82 and 84-97 under 35 U.S.C. 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over applicant's admittance on page 17 of their response and page 10, lines 15-25 and page 12, lines 8-13 of the specification.

Without acquiescing on the merits and in order to expedite prosecution, the Applicants have amended the affected claims to exclude subject matter wherein the  $X_2$  or  $X_3$  is a pentose monosaccharide group.

BigCHAP is N,N-Bis(3-D-gluconamidopropyl)cholamide and has the following chemical structure:

As depicted above, BigCHAP has a chemical formula wherein the cholic acid functional group is attached to the core structure via an amide bond and wherein the nitrogen of the amide bond is

disubstituted. The formulae of the present invention in contrast sets forth compounds with a backbone structure wherein  $X_1$  is a cholic acid group or deoxycholic acid group that is attached to the core structure via an amide bond that is **monosubstituted**. As BigCHAP has two saccharide groups, the compound subject matter of the rejected claims is arguably closest, when  $X_2$  and  $X_3$  of the Applicants formula are each a saccharide group. However, even then, the compounds of the claims still substantially differ.

As noted previously BigCHAP can be represented by the formula:

in which CA is a cholic acid and NG/GN is gluconamido. In contrast, the compound subject matter of claim 28 is arguably closest when both  $X_2$  and  $X_3$  are saccharide moieties which each form a gluconamido moiety with the N to which they are attached and m is 2 and n is 3. In that case, the compound set forth in Claim 28 has the same number of gluconamido groups as BigCHAP and reduces to the formula:

Accordingly, BigCHAP does not satisfy all the elements of the Applicants' claims and can not anticipate them.

With respect to the pentose monosaccharide contaminant of BigChap, this contaminant is of the formula:

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The base claims have been amended to set forth compound subject matter which excludes the compound of the above formula and, thus, the presence of this compound as a contaminant in some preparations of BigChap can not negate the novelty of the claimed subject matter even assuming *arguendo* that such would anticipate the previous claims under a theory of inherency.

As noted immediately above, the compound subject matter set forth in the amended claims no longer embraces the cited contaminant. With respect to the nonobviousness rejection under 35 U.S.C. §103(a), any admission as to the presence of the cited contaminant in BigCHAP does not place knowledge of the structure or advantageous properties of that contaminant in the prior art. There would simply be no motivation to make the claimed invention absent knowledge of the structure of the contaminant. There would simply be no expectation of success absent knowledge of the advantageous properties of the contaminant. As noted previously, MPEP §2141.02, sets forth that "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. In re Rijckaert, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993)." (see, MPEP Rev. 6, Sept. 2007 ed. at p. 2100-125). Accordingly, as a matter of law, given that the structure and properties of the cited contaminant are not disclosed nor suggested in any prior art cited by the Examiner, the obviousness of the different compound subject matter now set forth in the claims can not be predicated upon that art.

Importantly, moreover, the status of the alleged admission as an admission does not alter the analysis. MPEP §2129 starting at p. 2100-65 further sets forth

## I. ADMISSIONS BY APPLICANT CONSTITUTE PRIOR ART

A statement by an applicant during prosecution identifying the <u>work of another</u> as "prior art" is an admission that that work is available as prior art against the claims, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. Riverwood Int'l Corp. v. R.A. Jones & Co., 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed Cir. 2003). However, even if labeled as "prior art," the <u>work of the same inventive entity</u> may not be considered prior art against the claims unless it falls under one of the statutory categories. Id.; see also Reading & Bates Construction Co. v. Baker Energy Resources Corp., 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984) ("[W]here the inventor continues to improve upon his own work product, his foundational work product should not, without a statutory basis, be treated as prior art solely because he admits knowledge of

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his own work. It is common sense that an inventor, regardless of an admission, has

knowledge of his own work.").

Accordingly the alleged admissions of the specification with regard to the

existence of a contaminant in BigCHAP, does not place knowledge of the structure of that

contaminant or any surprisingly beneficial properties attributable to that structure in the prior art.

Absent knowledge of the existence of the contaminant, its structure and its pertinent

advantageous properties, there would be no motivation to modify the structure to obtain the

structurally different compounds of the base claims and certainly no expectation of success.

Accordingly, the Applicants alleged admission of the existence of the cited contaminant in

certain BigCHAP preparations can not be used to negate the nonobviousness of the present

claims.

Accordingly, the Applicants respectfully request that the above grounds for

rejection be reconsidered and withdrawn.

**CONCLUSION** 

In view of the foregoing, Applicants believe all claims now pending in this

Application are in condition for allowance. The issuance of a formal Notice of Allowance at an

early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of

this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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